AMENDMENTS TO THE CLAIMS

Claims Listing

This listing of the claims will replace all prior versions, and listings, of claims in the application:

1. (Currently amended) A method of detecting cancer-associated anti-tumor autoantibodies in a sample from an individual, comprising:

contacting the sample with an immunoassay reagent; and detecting a presence of complexes formed by specific binding of the immunoassay reagent to any cancer-associated anti-tumor autoantibodies present in the sample,

wherein the immunoassay reagent comprises one or more tumor marker proteins prepared from a bodily fluid from a body cavity or space in which a tumor is or was present in one or more cancer patients and the bodily fluid is not a fluid derived from the systemic circulation,

wherein said one or more tumor marker proteins exhibit selective reactivity with cancer-associated anti-tumor autoantibodies, wherein the tumor marker proteins are over-expressed or altered forms of wild-type proteins, and

wherein detection of complexes indicates the presence of cancer-associated anti-tumor autoantibodies in the individual.

- 2. (Previously presented) The method of Claim 1, further comprising detecting and/or quantitatively measuring the presence of two or more types of autoantibodies, wherein each one of the two or more types of the autoantibodies is immunologically specific to a different tumor marker protein or to different epitopes of the same tumor marker protein, wherein the immunoassay is carried out using a panel of two or more immunoassay reagents, at least one of which comprises the tumor marker protein of Claim 1.
- 3. (Previously presented) The method of Claim 1, wherein the sample is a bodily fluid sample obtained from a patient in need of detection or diagnosis of cancer, and wherein

Amendment and Response to Office Action U.S. Application Serial No. 10/534,773

Page 3

detection of the presence of an elevated level of the anti-tumor autoantibodies in the sample,

as compared to a sample from a normal control, indicates that the patient in need of detection

or diagnosis of cancer has or is developing a cancer.

4. (Previously presented) The method of Claim 1, wherein the sample is a bodily

fluid sample obtained from a patient in need of monitoring of progress of cancer or other

neoplastic disease, and wherein detection of the presence of an elevated level of the anti-

tumor autoantibodies in the bodily fluid sample, as compared to a sample from a normal

control, indicates the progress of cancer or other neoplastic disease in the patient in need of

monitoring of progress of cancer or other neoplastic disease.

5. (Previously presented) The method of Claim 1, wherein the sample is a bodily

fluid sample obtained from an asymptomatic subject, and wherein detection of the presence

of an elevated level of the anti-tumor autoantibodies in the bodily fluid sample, as compared

to a sample from a normal control, indicates early neoplastic or early carcinogenic change in

the asymptomatic subject.

6. (Previously presented) The method of Claim 1, wherein the sample is a bodily

fluid sample obtained from an asymptomatic human subject selected from a population of

asymptomatic human subjects in need of a screening for a risk of developing cancer, and

wherein detection of the presence of an elevated level of the anti-tumor autoantibodies in the

bodily fluid sample, as compared to a normal control, identifies the asymptomatic subject as

being at risk of developing cancer.

7. (Previously presented) The method of Claim 1, wherein the sample is a bodily

fluid sample obtained from a cancer patient in need of monitoring a response of the cancer

patient to an anti-cancer treatment, and wherein a change in level of the anti-tumor

autoantibodies in a sample after the anti-cancer treatment as compared to the level of the

US2000 11451308.2

Amendment and Response to Office Action U.S. Application Serial No. 10/534,773 Page 4

anti-tumor autoantibodies in a sample before the anti-cancer treatment indicates that the patient has responded positively to the treatment.

8. (Previously presented) The method of Claim 1, wherein the sample is a bodily fluid sample obtained from a patient in need of detection of a recurrent disease, wherein the patient was previously diagnosed as having cancer and has undergone anti-cancer treatment to reduce amount of cancer, and wherein presence of an increased level of autoantibodies in the patient, as compared to a normal control, indicates that the cancer has recurred.

Claims 9-10. (Cancelled)

- 11. (Previously presented) The method of Claim 1, wherein the bodily fluid from which the one or more tumor marker proteins is prepared is ascites fluid, pleural effusion, seroma, hydrocoele or wound drainage fluid.
- 12. (Previously presented) The method of Claim 3, wherein the bodily fluid from which the one or more tumor marker proteins is prepared is ascites fluid, pleural effusion, seroma, hydrocoele or wound drainage fluid.

Claims 13-14. (Cancelled)

- 15. (Withdrawn) The method of Claim 11, wherein the one or more tumor marker proteins are MUC1, MUC16 or c-myc.
- 16. (Withdrawn) The method of Claim 12, wherein the one or more tumor marker proteins are MUC1, MUC16 or c-myc.

Amendment and Response to Office Action U.S. Application Serial No. 10/534,773 Page 5

- 17. (Withdrawn) The method of Claim 1, wherein the one or more tumor marker proteins are c-erbB2, p53, ras, BRCA1, BRCA2, APC, PSA, CEA, or CA19.9.
- 18. (Withdrawn) The method of Claim 3, wherein the one or more tumor marker proteins are c-erbB2, p53, ras, BRCA1, BRCA2, APC, PSA, CEA or CA19.9.

Claims 19-38. (Cancelled)

- 39. (Previously presented) The method of Claim 1 wherein the tumor marker protein is prepared by collecting bodily fluid from the body cavity or space in which a tumor is or was present from one or more cancer patients and isolating the tumor marker protein from the bodily fluid using protein purification techniques.
- 40. (Previously presented) The method of Claim 39 wherein the tumor marker protein is prepared by collecting bodily fluid from the body cavity or space in which a tumor is or was present from two or more cancer patients, pooling the bodily fluid and isolating the tumor marker protein from the pooled bodily fluid using protein purification techniques.
- 41. (Previously presented) The method of Claim 39 wherein the isolated tumor marker protein is substantially immunoglobulin free.
- 42. (Cancelled) The method of Claim 1 wherein the bodily fluid from which the one or more tumor marker proteins is prepared is not from a systemic circulation.
- 43. (Previously presented) The method of Claim 1 where the bodily fluid from which the one or more tumor marker proteins is prepared is not whole blood or serum.

Amendment and Response to Office Action U.S. Application Serial No. 10/534,773 Page 6

44. (Previously presented) The method of Claim 1 wherein the bodily fluid is produced during the disease process in response to or as a consequence of the presence of tumor cells.